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Torts: Products Liability

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TORTS: PRODUCTS LIABILITY

INTRODUCTION

The Tenth Circuit Court of Appeals decided five important products liability cases during the survey period.[1] One case dealt with the preemption of common law failure-to-warn claims[2] and three cases involved or implied the misuse defense.[3] Another breakthrough case addressed the apparent manufacturer doctrine.[4] Part I of this survey discusses the Tenth Circuit's interpretation of the preemption clause of the Medical Device Amendments of 1976 (MDA) in relation to common law tort claims. Part II discusses a case of first impression, *Yoder v. Honeywell*,[5] and its clarification of the "apparent manufacturer" doctrine's scope. Finally, Part III describes the Tenth Circuit's treatment of the misuse defense, and compares this approach to those used by other jurisdictions.

I. PREEMPTION OF PRODUCTS LIABILITY CLAIMS

A. *Background*

Today, federal agencies regulate hundreds of consumer products and their proper manufacture, design, and labeling.[6] The Food and Drug Administration (FDA) is one of these agencies, regulating states' actions in the areas of public health and safety.[7] The Federal Food and Drug Act, enacted in 1906, protects the public from adulterated or misbranded products.[8] Congress later expanded the Act to include "adulterated or misbranded" devices and cosmetics,[9] but the legislation did not authorize control over the introduction of new medical devices.[10] With new technology creating medical equipment such as pacemakers, catheters, artificial heart valves, and defibrillators,[11] policymakers and the public grew

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1. The survey period extended from September 1, 1996 through August 31, 1997.

2. *See* Oja v. Howmedica, Inc., 111 F.3d 782, 784 (10th Cir. 1997).

3. *See* Staley v. Bridgestone/Firestone, Inc., 106 F.3d 1504, 1508 (10th Cir. 1997); Allen v. Minnstar, 97 F.3d 1365, 1368-70 (10th Cir. 1996); Daniel v. Ben E. Keith Co., 97 F.3d 1329, 1332 (10th Cir. 1996).

4. *See* Yoder v. Honeywell Inc., 104 F.3d 1215, 1222-23 (10th Cir. 1997) (quoting RESTATEMENT (SECOND) OF TORTS § 400 (1965)).

5. *See Yoder*, 104 F.3d at 1215, 1223 (failing to find any applicable Colorado case law).

6. *See* Richard C. Ausness, *Federal Preemption of State Products Liability Doctrines*, 44 S.C. L. REV. 187, 189-90 (1993).

7. *Id.*

8. Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2245-46 (1996).

9. Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), §§ 501, 502, 52 Stat. 1049-1051 (codified as amended at 21 U.S.C. §§ 351, 352 (1994)); H.R. REP. NO. 94-853, at 6 (1976) (recommending passage of the MDA).

10. *See Medtronic*, 116 S. Ct. at 2246.

11. *Id.*; *see also* S. REP. NO. 94-33, at 5 (1975) (discussing the post-war development of new medical equipment including pacemakers and artificial heart valves).

concerned about injuries resulting from the product malfunctions.[12] These concerns mounted in 1970,[13] when the Dalkon Shield, an intrauterine contraceptive device,[14] caused thousands of women to suffer from toxic shock, infertility, pelvic infections, and even death.[15] Because the FDA possessed limited authority to prevent these events,[16] Congress enacted the MDA in 1976,[17] requiring the FDA to review medical devices *before* they could be marketed to the public.[18]

The MDA classified medical devices into three risk-based categories.[19] Class I, relatively risk-free devices such as crutches, are subject to minimal regulation.[20] Devices in Class II, such as tampons and oxygen masks used in anesthesiology,[21] are considered riskier, and although they do not need advance approval by the FDA, manufacturers of these devices must follow federal performance regulations called "special controls."[22] Class III devices either "present a potential unreasonable risk of illness or injury,"[23] or are "purported or represented to be for a use in supporting or sustaining human life"[24] or for use which "is of substantial importance in preventing impairment of human health."[25] Class III devices include such life-saving and potentially life-saving items as pacemakers[26] and heart valves.[27]

Many Class III devices are subject to a rigorous and lengthy process known as pre-market approval (PMA),[28] which requires the manufacturer

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12. *Medtronic*, 116 S. Ct. at 2246.

13. Roger W. Bivans, Note, *Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices*, 74 TEX. L. REV. 1087, 1088 (1996).

14. *Medtronic*, 116 S. Ct. at 2246.

15. *Id.*; *see also In re* A.H. Robins Co., 880 F.2d 709, 711-12 (4th Cir. 1989) (discussing the history of the Dalkon Shield problems and the resulting litigation).

16. *See* Bivans, *supra* note 13, at 1088.

17. *Medtronic*, 116 S. Ct. at 2246. The House Report on the MDA states:

> Those involved in the development, promotion, and application of medical devices generally agree that the public deserves more protection against unsafe, unproven, ineffective, and experimental medical devices. But this belief is counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field.

H.R. REP. NO. 94-853, at 10 (1976).

18. *See* Bivans, *supra* note 13, at 1088.

19. *Id.* at 1090.

20. *See* 21 U.S.C. § 360c(a)(1)(A)(I)-(II) (1994); Ginochio v. Surgikos, Inc., 864 F. Supp. 948, 950 (N.D. Cal. 1994) (describing the various classifications and providing examples of Class I devices).

21. *See* Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 42 (D. Mass. 1994) (describing the classifications of medical devices and providing examples of Class II devices).

22. *See* 21 U.S.C. § 360c(a)(1)(B); *see also Medtronic*, 116 S. Ct. at 2246 (discussing Class II devices and the requirement that manufacturers of such devices comply with "special controls").

23. 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

24. *Id.* § (a)(1)(C)(ii)(I).

25. *Id.*

26. *See* Larsen v. Pacesetter Sys., Inc., 837 P.2d 1273, 1282 (Haw. 1992).

27. Ministry of Health v. Shiley, Inc., 858 F. Supp. 1426, 1431 (C.D. Cal. 1994).

28. *See Medtronic*, 116 S. Ct. at 2246-47.

to submit a pre-market application with all relevant information substantiating the product's safety and effectiveness.[29] Such information includes reports of investigations of safety and effectiveness, statements of components and principles of operation of the device, and proposed labeling.[30] After the information is submitted, the FDA will not grant approval until both FDA officials and an outside panel of experts review and approve the PMA application.[31]

Class III devices, however, may escape the rigorous qualifications imposed by the PMA requirement.[32] Section 360(k) of the MDA imposes a limited form of review for manufacturers seeking to market new devices similar to those already available on the market.[33] This is known as the "510(k) process."[34] A device can be marketed without further regulatory analysis if the FDA determines that the device is "substantially equivalent" to a pre-existing device.[35] The MDA, however, gives little guidance in defining "substantially equivalent."[36] The broad guidelines set forth in the MDA require the manufacturer to submit information proving "substantial equivalence," and allow the FDA to request additional information before approval.[37] FDA 510(k) approval is not an en-

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29. *See* Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 208-09 (1987).

30. *See* 21 U.S.C. §§ 360c(a)(3)(A), (D)(i).

31. *See id.* § 360c(b)(1)(B).

32. *See Medtronic*, 116 S. Ct. at 2247 (noting that most Class III devices have not received premarket approval due to two important exceptions to the PMA requirement).

33. *Id.*

34. *Id.* The *Medtronic* Court noted that the 510(k) process eventually became the means by which most new medical devices were approved. The Court referred to a House Report stating that 1,000 of approximately 1,100 Class III devices were considered to be "substantially equivalent" to pre-existing devices, and therefore, not subject to the rigorous PMA process. *Id.* at 2247-48. (citing STAFF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMM. ON ENERGY AND COMMERCE, MEDICAL DEVICE REGULATION: THE FDA'S NEGLECTED CHILD 34 (Comm. Print 1983). The Court also noted that in 1990, 80% of new Class III devices entered the market through the section 510(k) process. *Id.* at 2248 (citing H.R. REP. NO. 101-808, at 14 (1990)).

35. *Id.* at 2247.

36. *See* Jonathan S. Kahan, *Premarket Approval v. Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L.J. 510, 519-20 (1984). Scholars have also argued that the term "substantially equivalent" is unconstitutionally vague. *See, e.g.*, Jonathan H. Kaplan, *Through the Maze of 510(k)s*, 39 FOOD DRUG COSM. L.J. 160, 163 (1984).

37. *See* 21 C.F.R. § 807.87(f) (1987). The legislative history regarding the definition of "substantially equivalent" states the following:

> [T]he term substantially equivalent is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purpose as the marketed products. The Committee believes the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not so narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in material, design, or energy sources, for example would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified in Class III. On the other hand, copies of devices marketed prior to enactment or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.

dorsement of the device's safety,[38] but the process is significantly faster and less financially burdensome on manufacturers than the PMA process,[39] and as a result most manufacturers prefer to file a 510(k) application instead of a PMA.[40]

Section 360k(a) expressly forbids states from establishing any requirements that are "different from or in addition to" any FDA safety or effectiveness standard applicable to a medical device regulated by the MDA.[41] Thus, this amendment clearly preempts state regulations and statutes,[42] but it remains unclear whether 360k(a) also preempts state tort law.[43] Under state common law, products liability laws were designed to remedy injured consumers,[44] prompting manufacturers to design and distribute safer products and thus avoid lawsuits and large damage awards.[45] The MDA, however, does not provide compensation for injured consumers,[46] and encourages manufacturers to develop and utilize new technologies and ensure minimum safety testing.[47] This overlap between the

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H.R. REP. NO. 94-853, at 36-37 (1976).

38. *See, e.g., Medtronic*, 116 S. Ct. at 2248 (noting that a 510(k) determination allowing the marketing of a pacemaker did not in any way endorse that pacemaker's safety).

39. Robert J. Katerberg, Note, *Patching the "Crazy Quilt" of Cippolone: A Divided Court Rethinks Federal Preemption of Products Liability in* Medtronic, Inc. v. Lohr, 75 N.C. L. REV. 1440, 1461 (1997). The PMA process requires the FDA to review information submitted by manufacturers for an average of 1,200 hours while the 510(k) process takes about 20 hours. *See* Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1095 (10th Cir. 1997). In addition, the cost to manufacturers was between $111,000 and $828,000 of the PMA process while the cost to manufacturers to undergo the 510(k) process was between $50 and $2,000. *See* Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 47 (1989).

40. *See* Kahan, *supra* note 36, at 519.

41. Section 360k(a) states, in relevant part:

> (a) General rule
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> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994).

42. *See* Ausness, *supra* note 6, at 281.

43. *See id. See generally* Allison Weiser, *Stone Offers Advice on Preemption Cases to Conference Attendees*, Andrews Med. Devices Litig. Rep. 9 (July 1, 1997) (discussing how courts are confused over the breadth of the preemption provisions in product liability litigation).

44. *See* Katerberg, *supra* note 39, at 1440.

45. *See id.*; *see, e.g.*, Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) ("It is to the public interest to discourage the marketing of products having defects that are a menace to the public."); Mary L. Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 176 (1995) ("[T]ort law's signals [to manufacturers] contain necessary basic messages that are not delivered through any other medium. An important function of the law is to guide early evolution of technologies . . . .").

46. *See* Katerberg, *supra* note 39, at 1441.

47. *See id.*

MDA's purpose and states' interests has confused courts trying to determine the preemptive scope of the MDA.[48]

Legislative history does not reveal congressional intent regarding MDA preemption of common law tort claims.[49] The Supremacy Clause provides that federal law takes precedence over contradictory state law,[50] and preemption has traditionally involved federal regulations that supersede conflicting state and local administrative regulations, statutes, or ordinances.[51] Federal regulations rarely preempt state common law unless a congressional intent to preempt is "clear and manifest."[52] The FDA, however, has interpreted the MDA to preempt state regulations, statutes, and the common law.[53] The idea that federal regulations should displace state common tort law has caused controversy and confusion.[54] Courts disagree about the precise scope of 360(k)a,[55] and the Supreme Court attempted to settle this matter in *Medtronic, Inc. v. Lohr*.[56]

In *Medtronic*, the Supreme Court analyzed and interpreted the MDA.[57] Medtronic, Inc., a medical device manufacturer, introduced the Model 4011 pacemaker into the market,[58] and the plaintiff was implanted with the device.[59] The pacemaker basically mirrored the designs of existing models,[60] and the FDA found the pacemaker to be "substantially equivalent to devices introduced into interstate commerce prior to the effective date of the [MDA]."[61] As a result, the new pacemaker did not undergo the extensive review process required for new designs.[62] The pacemaker failed, resulting in a "complete heart block," and emergency surgery for the plaintiff.[63]

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48. *See id.* at 1442.

49. *See* Ausness, *supra* note 6, at 282; Katerberg, *supra* note 39, at 1462-63.

50. U.S. CONST. art. VI, § 2, cl. 2.

51. *See* Ausness, *supra* note 6, at 189. *See generally* Michael Maher, *Federal Preemption, New Barrier to Injured Victims*, TRIAL, Nov. 1991, at 61 (1991) (discussing federal preemption in the context of several areas of tort litigation).

52. Ausness, *supra* note 6, at 192 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). Courts are hesitant to allow preemption within a particular area traditionally reserved to the states. *See* Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 206 (1983).

53. *See* Ausness, *supra* note 6, at 283. In addition, the FDCA contains no preemption provision while section 360k(a) expressly preempts state requirements. *Id.*

54. *See* Maher, *supra* note 51, at 61.

55. *See* Weiser, *supra* note 43 (discussing courts' various interpretations of section 360(k)a).

56. 116 S. Ct. 2240 (1996).

57. *Medtronic*, 116 S. Ct. at 2240.

58. *Id.* at 2248.

59. The failure of the pacemaker was attributed to a defective lead, the component that transmits the heartbeat-steadying electrical signal from the "pulse generator" to the heart. *Id.*

60. *See id.*; Katerberg, *supra* note 39, at 1448.

61. *Medtronic*, 116 S. Ct. at 2248.

62. *Id.*

63. *Id.*

The plaintiff filed a complaint against Medtronic based upon state common law negligence and strict liability.[64] Medtronic argued that section 360(k)(a) preempted both claims.[65] The Eleventh Circuit held that although the negligent design claims were not preempted, the negligent manufacture and failure-to-warn claims were preempted,[66] and the court limited the strict liability claim to the theory that the pacemaker was "unreasonably dangerous."[67]

In a plurality opinion, the Supreme Court affirmed the Eleventh Circuit's finding of no preemption of design claims,[68] but reversed regarding the negligent manufacturer and failure-to-warn claims.[69] In determining the preemptive scope of the MDA, the Court applied a two-pronged inquiry. First, the Court noted that federal requirements must be specific to a particular device.[70] The Court found that the plaintiff's state common law claims were developed "specifically in regard to medical devices," while the federal labeling and manufacturing requirements essentially reflected generic and general concerns about device regulation.[71]

In addition, the Court held that any state regulation of medical devices must be "different from or in addition to" a federal requirement in order to be preempted.[72] The state requirements were not specifically developed with respect to medical devices[73] because they were not the "kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements."[74] Both the failure-to-warn and negligent manufacturing claims involved general duties of the manufacturer to use due care or to inform users of potentially dangerous items.[75] The Court held that federal law did not preempt these general obligations.[76]

Despite the Supreme Court's discussion, the decision left some gaps.[77] First, *Medtronic* departed from an earlier Supreme Court decision in which, under a similar federal statute, the Court found state claims

64. *Id.*
65. *Id.*
66. *See* Lohr v. Medtronic, Inc., 56 F.3d 1335, 1347-51 (11th Cir. 1995) (holding that while the negligent design claim was not preempted by the MDA, the negligent manufacture claim and failure-to-warn claims were preempted).
67. *Lohr*, 56 F.3d at 1347-49. The court also refused to let the plaintiffs change their preempted negligence claims into a strict liability claim. *Id.* at 1352.
68. *Medtronic*, 116 S. Ct. at 2255.
69. *Id.* at 2258.
70. *Id.* at 2257.
71. *Id.*
72. *Id.*
73. *Id.* at 2258.
74. *Id.*
75. *Id.*
76. *Id.*
77. *See* Weiser, *supra* note 43 (discussing the "badly fractured decision" in *Medtronic*).

were preempted by federal law.[78] Furthermore, the internal division of the *Medtronic* Court failed to resolve some issues.[79] The Tenth Circuit attempted to clarify this issue during the survey period.

B. Oja v. Howmedica, Inc.[80]

1. Facts

The plaintiff replaced her artificial hip with a Porous-Coated Anatomic One-Piece Acetabular Component hip (PCA hip)[81] produced by Howmedica. Eight years later she experienced severe pain in her hip and underwent surgery, which revealed that "the staking peg was missing, that the polyethylene liner had completely disengaged from the metal cup, and that debris had spread into Oja's hip joint."[82] This caused severe bone dissolution and significant defects in Oja's hip.[83]

The plaintiff filed a products liability suit against Howmedica, asserting claims of negligence, negligent failure-to-warn, and strict liability.[84] Howmedica, however, argued that these claims were preempted under the MDA.[85] The district court returned a general verdict for Howmedica on the negligence and strict liability claims,[86] but it also found that the MDA did not preempt Oja's negligent failure-to-warn claim, and therefore, entitled Oja to relief.[87]

2. Decision

The Tenth Circuit applied the *Medtronic* two-pronged test to determine the preemptive scope of the MDA.[88] First, although the plaintiff's case involved a specific federal requirement applicable to the PCA hip, the failure-to-warn claim was not "specifically developed 'with respect to' medical devices."[89] The claim was predicated upon a general common law duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."[90] Second, the court held that federal law did not preempt the failure-to-

78. *See* Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521-23 (1992).
79. *See generally* Katerberg, *supra* note 39 (analyzing the plurality decision in *Medtronic* and its ramifications on products liability claims).
80. 111 F.3d 782, 785 (10th Cir. 1997).
81. *Oja*, 111 F.3d at 785.
82. *Id.*
83. *Id.*
84. *Id.* at 784.
85. *Id.*
86. *Id.* at 785.
87. *Id.*
88. *Id.* at 788.
89. *Id.* at 789 (quoting *Medtronic*, 116 S. Ct. at 2258).
90. *Id.*

warn claim because it did not involve the type of device-specific requirements that would threaten the MDA's federal interests.[91]

C. *Other Circuits*

Two other circuits addressed this issue during the survey period. In *Martin v. Telectronics Pacing Systems, Inc.*, the Sixth Circuit applied *Medtronic*'s two-prong test.[92] The court determined that the state requirements specifically applied to investigational devices, unlike the general statutory concerns involved in *Medtronic*.[93] In addition, the court found that the state requirements were different from those mandated under the federal scheme and would "impede the implementation and enforcement of specific federal requirements."[94] The court also determined that allowing a cause of action in a case in which the FDA specifically approved the design of a device for investigational purposes would thwart the goals of safety and innovation.[95]

The Fourth Circuit addressed the issue as well, holding that the MDA did not preempt common law tort claims by the recipient of a defective penile prosthesis.[96] In *Martin v. American Medical Systems* (AMS), the plaintiff suffered from erectile dysfunction,[97] and was surgically implanted with AMS's Dyaflex, an inflatable penile prosthesis.[98] He subsequently developed a severe infection, and was forced to undergo numerous surgical procedures that shortened and disfigured his penis.[99] He then filed several tort and warranty theory claims against AMS.[100] AMS moved for summary judgment, arguing that the MDA preempted Martin's claim.[101] The district court held that all claims were preempted except the breach of express warranty claim.[102] The Fourth Circuit overturned, holding that because the Dyaflex received 510(k) approval, federal law did not preempt state common law tort claims.[103] The court discussed *Medtronic* and noted that the 510(k) process could not be consid-

91. *Id.*
92. 105 F.3d 1090 (6th Cir. 1997).
93. *Telectronics*, 105 F.3d at 1098-1101 (discussing the "investigational devices" exemption in terms of Martin's claims).
94. *Id.* at 1099 (citing *Medtronic*, 116 S. Ct. at 2258).
95. *Id.* at 1098-99.
96. Martin v. American Med. Sys., Inc., 116 F.3d 102, 104 (4th Cir. 1997).
97. *Id.* at 103.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. *Id.* On the breach of express warranty claim, the court held that the plaintiff could not show reliance on the express "Limited Warranty" made to his urologist by American Medical. *Id.*
103. *Id.* at 104.

ered as FDA approval because it only existed to preserve the pre-1976 status quo,[104] which included potential state law liability.[105]

D. *Analysis*

The Tenth Circuit's application of *Medtronic* preserved state common law doctrine. Prior to *Medtronic*, manufacturers faced little deterrence from producing dangerous consumer products.[106] Although the MDA's purpose was to increase product safety and prevent consumer injuries,[107] the 510(k) exception contradicted this goal.[108] With the exception intact, consumers could purchase unsafe devices that were merely "substantially equivalent" to devices already on the market.[109] Indeed, if pre-existing devices on the market were ineffective, unsafe, or even deadly, manufacturers were essentially encouraged to continue production in order to satisfy the 510(k) "substantially equivalent" definition.[110] Because of the MDA's vague guidelines,[111] almost all manufacturers satisfied this test.[112] Even when one of these devices injured a consumer, the manufacturer could escape common law product liability claims by raising the MDA's preemption clause, thereby avoiding litigation on the merits of the claim.[113]

In an effort to guide lower courts in applying preemption laws, *Medtronic* expanded consumer protection. After *Medtronic*, the general consensus among circuits is that any state claim that is "different from or in addition to" the federal requirements will be preempted.[114] What exactly constitutes "different" has not been specifically defined by either the Supreme Court or the Tenth Circuit, and MDA preemption issues remain very fact-specific. Although the *Medtronic* test may give lower courts additional flexibility in many situations,[115] the test is vague enough to make liability difficult for manufacturers to predict. Manufacturers may take advantage of this ambiguity and attempt to use it as technical subterfuge to escape liability. As a result, consumers may encounter great difficulty in relying on state common law for their claims.

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104. *Id.*

105. *Id.*

106. *See* Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 694-715 (1997) (discussing the state of Pre-*Medtronic* products liability preemption, the *Medtronic* decision, and the aftermath).

107. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at Food, Drug, and Cosmetic Act of 1938 § 4(a), 21 U.S.C. §§ 360-360k (1994)).

108. *See supra* notes 38-39 and accompanying text.

109. *See* Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2248 (1996).

110. *See supra* notes 38-39 and accompanying text.

111. *See supra* note 37 and accompanying text.

112. *See supra* note 34 and accompanying text.

113. *See* Kahan, *supra* note 36, at 519; *supra* note 41 and accompanying text.

114. *Medtronic*, 116 S. Ct. at 2248 (quoting 21 U.S.C. § 360k(a) (1994)).

115. *See Medtronic*, 116 S. Ct. at 2257.

II. THE APPARENT MANUFACTURER DOCTRINE'S FIRST IMPRESSION: *YODER V. HONEYWELL*[116]

A. *Background*

The apparent manufacturer doctrine makes non-manufacturing sellers liable for their involvement with defective products.[117] Defined in the Second Restatement of Torts,[118] this doctrine subjects a nonmanufacturer of a product to the same liability as a manufacturer.[119] As a result, retailers, distributors and trademark licensors[120] face potential liability.[121] Most apparent manufacturer cases involve "a defendant labeling or affixing to the product its own name, trade name, or trademark, or an advertisement identifying the defendant as the maker of the product."[122]

Consumer expectations dictate the need for this approach;[123] a consumer may reasonably believe that the nonmanufacturer created the product and may rely upon their reputation and skill when choosing the product.[124] Therefore, if a company induces the public to believe that it manufactured the product, the apparent manufacturer doctrine will impose liability upon that company.[125] The apparent manufacturer doctrine also helps to define appropriate accountability and to deter the misuse of corporate structures to evade tort liability.[126]

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116. 104 F.3d 1215 (1997).

117. *See* Seasword v. Hilti, Inc., 537 N.W.2d 221, 223 (Mich. 1995).

118. Section 400 provides: "One who puts out as his own product a chattel manufactured by another is subject to the same liability as though he were its manufacturer." RESTATEMENT (SECOND) OF TORTS § 400 (1965).

119. *Seasword*, 537 N.W.2d at 223. In principle, the apparent manufacturer doctrine expands tort liability and guarantees "that some entity in the product enterprise remains answerable for injuries caused by defective products." *See* Rosemary G. Schikora, *No "Apparent Manufacturer" Liability in Michigan*, MICH. BAR J., Mar. 1996, at 247 (quoting *Seasword*, 537 N.W.2d at 223).

120. Most courts that impose liability on trademark licensors only do so if the licensor also played a significant role in the chain of distribution. *See* Burkert v. Petrol Plus, 579 A.2d 26, 33-34 (Conn. 1990).

121. *See, e.g.*, Dudley Sports Co. v. Schmitt, 279 N.E.2d 266, 273-74 (Ind. Ct. App. 1972) (using the apparent manufacturer doctrine to impose liability on a distributor); *see also* Kasel v. Remington Arms Co., 24 Cal. App. 3d 711, 717-19 (Ct. App. 1972) (imposing liability on trademark licensor who played a significant role in forming the entity that manufactured the product); Rubbo v. Hughes Provision Co., 34 N.E.2d 202, 204 (Ohio 1941) (estopping defendant, who was trademark licensor and retailer of the product, from denying agency, therefore imposing liability on the defendant).

122. Seasword v. Hilti, Inc., 525 N.W.2d 501, 502 (Mich. Ct. App. 1994).

123. *See* Schikora, *supra* note 119, at 247.

124. Root v. J.H. Indus., Inc., 660 N.E.2d 195, 198 (Ill. App. Ct. 1995) (quoting Hebel v. Sherman Equip., 442 N.E.2d 199, 203 (Ill. 1982)).

125. *See* Alan J. Lazarus et al., *Recent Developments in Products, General Liability, and Consumer Law*, 32 TORT & INS. L.J. 499, 499 (1997).

126. *See* Seasword v. Hilti, Inc., 537 N.W.2d 221, 224 (Mich. 1995).

At least eighteen states have recognized the apparent manufacturer doctrine,[127] which was incorporated into the Model Uniform Product Liability Act.[128] Most jurisdictions that recognize this doctrine have also adopted strict tort liability as a theory of recovery.[129] Jurisdictions refusing to recognize strict liability often choose not to adopt the apparent manufacturer doctrine because, when combined with other theories, it often ultimately imposes strict liability upon nonmanufacturers.[130]

Some courts, however, have found that the use of the apparent manufacturer doctrine is unnecessary because current theories of seller liability and related tort doctrines generate the same result.[131] For example, a seller can be found liable under the laws of agency, fraud, and misrepresentation in a situation where the seller uses a product label upon which consumers rely.[132] "Piercing the corporate veil" and successor liability may also be used by courts to establish liability,[133] thus holding corporate stockholders personally liable for defective product injuries, even though the stockholder did not manufacture the product.[134] Similarly, successor liability may hold a corporation that merges with, or acquires, another corporation liable for injuries caused by a defective product produced by the old corporation.[135]

These theories are limited, however. For example, "piercing the corporate veil" is appropriate only when public policy is violated or a corporate structure is misused to escape justice.[136] Similarly, successor liability is often available only in limited circumstances.[137] The precise application

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127. Jan C. Leventer, Annual Survey of Michigan Law, *Torts*, 43 WAYNE L. REV. 1181, 1207 (1997); *see Seasword*, 537 N.W.2d at 223 n.8 (listing courts which have adopted the apparent manufacturer doctrine).

128. 44 Fed. Reg. 62,714 (1979).

129. *See, e.g.*, Davis v. United States Gauge, 844 F. Supp. 1443 (D. Kan. 1994); Rice v. Armstrong World Indus., Inc., 653 F. Supp. 763 (D. Colo. 1987); Burkert v. Petro Plus, 579 A.2d 26 (Conn. 1990); Pierce v. Liberty Furniture Co., 233 S.E.2d 33 (Ga. Ct. App. 1977); Coca Cola Bottling Co., Inc. v. Reeves, 486 So. 2d 374 (Miss. 1986); Sears, Roebuck & Co. v. Black, 708 S.W.2d 925 (Tex. App. 1986); Zamora v. Mobil Corp., 704 P.2d 584 (Wash. 1985).

130. Seasword v. Hilti, Inc., 525 N.W.2d 501, 504 (Mich. Ct. App. 1994) ("Regardless of whether the seller holds the product out as its own, the seller has no input in the design of the product. Thus, imposing liability would amount to strict liability, which this jurisdiction has declined to adopt.").

131. *Id.*

132. *See, e.g.*, Dudley Sports Co. v. Schmitt, 279 N.E.2d 266 (Ind. Ct. App. 1972); Fahey v. Rockwell Graphic Sys., Inc., 482 N.E.2d 519 (Mass. App. Ct. 1985); Commissioners of State Ins. Fund v. City Chem. Corp., 48 N.E.2d 262 (N.Y. 1943).

133. *See Seasword*, 537 N.W.2d at 224-25.

134. *See* Messick v. Moring, 514 So. 2d 892, 894 (Ala. 1987) (listing commonly used justifications for "piercing the corporate veil" and imposing liability on shareholders or a controlling corporation).

135. *See* Rawlings v. D.M. Oliver, Inc., 159 Cal. Rptr. 119, 120 (Ct. App. 1979).

136. *See* Leventer, *supra* note 127, at 1207.

137. *See, e.g.*, Parson v. Roper Whitnesy, Inc., 586 F. Supp. 1447 (W.D. Wis. 1984) (granting successor corporation summary judgment in a products liability action by a worker who suffered injuries while operating a hydraulic press brake); *In re* Related Asbestos Cases, 578 F. Supp. 91 (N.D. Cal. 1983) (allowing successor corporation to escape liability for worker's asbestos-related

of this apparent manufacturer doctrine continues to develop, and many jurisdictions remain undecided about the scope and use of the doctrine.[138]

B. Yoder v. Honeywell[139]

1. Facts

The plaintiff, in the course of her employment, used a defective computer keyboard and consequently suffered from repetitive stress injuries, including bilateral carpal tunnel syndrome, bilateral radial tunnel syndrome and bilateral thoracic outlet syndrome.[140] She brought suit against the manufacturer of the office keyboards, Bull HN Information Systems, Inc., and against Bull's parent corporation, Honeywell.[141] One of her claims alleged that Honeywell, even though a subsidiary and not the actual keyboard manufacturer, should be held liable under the apparent manufacturer doctrine.[142] She premised this claim upon Section 400 of the Restatement (Second) of Torts[143] and Colorado law.[144] Although Honeywell's trademark was on four of the seven keyboards used by the plaintiff, the district court held that Honeywell was not liable to the plaintiff as a manufacturer and declined to apply the apparent manufacturer doctrine.[145]

2. Decision

The Tenth Circuit recognized that Colorado law did not address whether the apparent manufacturer doctrine would apply under state law.[146] The court examined the Colorado Products Liability Act and the Colorado Revised Statutes section 13-21-401, which imposes strict liability for defective products on "manufacturers."[147] In analyzing the

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injuries); Matrix-Churchill v. Springsteen, 461 So. 2d 782 (Ala. 1984) (holding that successor corporation could not be liable for a worker's injuries sustained from a metal brake); Burr v. South Bend Lathe, Inc., 480 N.E.2d 105 (Ohio Ct. App. 1984) (allowing no liability to successor in a strict liability action where there were a series of successors).

138. *See supra* notes 132-35 and accompanying text.

139. 104 F.3d 1215 (10th Cir. 1997).

140. *Yoder*, 104 F.3d at 1215.

141. *See id.* at 1218.

142. *Id.* at 1219.

143. *See* RESTATEMENT (SECOND) OF TORTS § 400 (1965).

144. *Yoder*, 104 F.3d at 1222-23.

145. *Id.* at 1219.

146. *Id.* at 1223.

147. *Id.* Section 13-21-401 defines a manufacturer as:

> [A] person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product prior to the sale of the product to a user or consumer. The term includes any seller who has actual knowledge of a defect in a product or a seller of a product who creates and furnishes a manufacturer with specifications relevant to the alleged defect for producing the product or who otherwise exercises some significant control over all or a portion of the manufacturing process or who alters or modifies a product in any significant manner after the product comes into his possession and before it is sold to the ultimate user or consumer. The term also includes

definition of "manufacturer" in the statute, the court determined that Colorado, by negative implication, had adopted the "essence" of the Restatement.[148]

Nonetheless, the court refused to extend liability to Honeywell under the apparent manufacturer doctrine[149] because Honeywell did not sell or distribute the keyboards, and because many courts have declined to extend section 400 of the Restatement beyond sellers or distributors of defective products.[150] The court rejected the plaintiff's argument that the Restatement allows courts to extend strict liability to owners of trademarks who are not otherwise involved in the "chain of distribution."[151] The court also disregarded the argument that Colorado Revised Statute section 13-21-401 defines "manufacturer" as someone who "otherwise prepares a product" before its sale;[152] rather, the court limited the application of the apparent manufacturer doctrine to trademark owners.[153] In addition, the court noted that the plain meaning of the phrase "otherwise prepares a product" did not include those whose names were merely placed upon the product.[154]

C. *Analysis*

Because courts have experienced difficulty in determining the precise scope and application of the apparent manufacturer doctrine, *Yoder* undoubtedly clarified the apparent manufacturer doctrine's scope.[155] In imposing liability on a company whose name appears on a product, most courts seek to protect consumer expectations.[156] Despite the fact that Honeywell's name appeared on four of the seven keyboards, which

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> any seller of a product who is owned in whole or significant part by the manufacturer or who owns, in whole or significant part, the manufacturer. A seller not otherwise a manufacturer shall not be deemed to be a manufacturer merely because he places or has placed a private label on a product if he did not otherwise specify how the product shall be produced or control, in some significant manner, the manufacturing process of the product and the seller discloses who the actual manufacturer is.

COLO. REV. STAT. § 13-21-401 (1997).

148. The court noted that the last sentence of the statutory definition was similar to section 400 of the Restatement and therefore, "[b]y negative implication the statute allows a seller who places a private label on a product without disclosing the actual manufacturer to be liable as a manufacturer." *Yoder*, 104 F.3d at 1223.

149. *Id.* at 1224.

150. *Id.* The court recognized several jurisdictions following this principle. *See, e.g.*, Fletcher v. Atex, Inc., 68 F.3d 1451, 1463 (2d Cir. 1995) (upholding summary judgment on apparent manufacturer claims where defendant was neither seller of computer keyboard nor otherwise involved in the chain of distribution); Affiliated FM Ins. Co. v. Trane Co., 831 F.2d 153, 155-56 (7th Cir. 1987) (rejecting liability for product designer who did not sell, manufacture or install gas heater); Nelson v. International Paint Co., Inc., 734 F.2d 1084 (5th Cir. 1984) (declining to impose liability on parent company uninvolved in distribution).

151. *Yoder*, 104 F.3d at 1223-24.

152. *Id.* at 1224.

153. *Id.*

154. *Id.*

155. *See supra* notes 131-37 and accompanying text.

156. *See* Leventer, *supra* note 127, at 1207-08.

would give rise to the plaintiff's expectations that the keyboards were in fact manufactured by Honeywell, the court ignored the trend[157] and held that Honeywell was not liable.[158]

The purpose of imposing liability under tort principles is to induce "socially desirable conduct."[159] Because nonmanufacturers are often unaware of the dangers created by the manufacturer, nonmanufacturer liability would not further deterrence principles and could be "grossly unfair."[160] By limiting the apparent manufacturer doctrine to only manufacturers, *Yoder* deters manufacturers of products and those extremely familiar with them from producing or distributing items that do not meet the highest possible standards.[161] Additionally, consumers retain the ability to seek compensation from those manufacturers.

In contrast, some commentators argue that *Yoder* may damage consumer interests.[162] Plaintiffs may face a larger burden of finding and identifying the correct product manufacturer,[163] may be forced to exercise due diligence in attempting to identify the actual manufacturer, and will be unable to rely upon labels or names placed upon the product.[164] As a result, consumers may have to file numerous claims against a variety of defendants in order to identify the actual manufacturer.[165] This burden on consumers, however, is necessary to uphold principles of fairness. While consumers may have to investigate a product more thoroughly before relying upon its label, such an investigation is necessary to maintain an adequate balance between protecting nonmanufacturers from infinite liability and insuring adequate consumer protection.

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157. *See, e.g.*, Torres v. Goodyear Tire & Rubber Co., 786 P.2d 939, 947 (Ariz. 1990) (suggesting liability for a trademark licensor that had the ability to control the merchandise); Hartford v. Associated Construction Co., 384 A.2d 390 (Conn. 1978) (holding that the apparent manufacturer doctrine applies even to trademark licensors not involved in the production, marketing or distribution of the defective product). *But see* Nelson v. International Paint Co., 734 F.2d 1084 (5th Cir. 1984) (holding that trademark name alone on product is not enough to justify liability under the apparent manufacturer doctrine).

158. *Yoder*, 104 F.3d at 1223.

159. James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 273 (1990).

160. *Id.* at 274.

161. *See* Kevin P. Kavanagh & Peter H. Webster, Annual Survey of Michigan Law, *Torts*, 42 WAYNE L. REV. 1191, 1218 (1996).

162. *See* Schikora, *supra* note 119, at 247; Ellen Wertheimer, *Unknowable Dangers and the Death of Strict Products Liability: The Empire Strikes Back*, 60 U. CIN. L. REV. 1183, 1189 (1992).

163. *See* Kavanagh & Webster, *supra* note 161, at 1218.

164. *See* Schikora, *supra* note 119, at 247.

165. *See* Kavanagh & Webster, *supra* note 161, at 1218.

III. MISUSE

A. *Background*

Misuse is one of the most common defenses to product liability actions,[166] asserting that the plaintiff's conduct was so unforeseeable and improper that the plaintiff, not a product defect, caused the injury.[167] This defense is also used to either disprove causation, or to demonstrate that a product defect never existed.[168] Limiting the manufacturer's or supplier's liability ensures that products liability law does not serve as a substitute insurance policy for consumers.[169]

Courts disagree upon the meaning of misuse and have developed a variety of definitions for the doctrine,[170] resulting in numerous definitional disagreements.[171] Misuse has been defined by some courts as "a use or handling so unusual that the average consumer could not reasonably expect the product to be designed and manufactured to withstand it—a use that the seller, therefore, need not anticipate and provide for."[172] Other courts have defined misuse as "use of a product where it is handled in a way which the manufacturer could not have reasonably foreseen or expected in the normal and intended use of the product and the plaintiff could foresee an injury as the result of the unintended use,"[173] or "use of the product which constitutes willful or reckless misconduct or an invitation of injury."[174]

Some courts define misuse simply as "a use of the product in a manner which defendant could not reasonably foresee,"[175] or "a use not reasonably foreseeable."[176] Many courts refer to the Restatement of (Second) of Torts section 402A as a basis for implementing this defense.[177]

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166. Christopher H. Toll, *The Burden of Proving Misuse in Products Liability Cases*, 20 COLO. LAW. 2307, 2307 (1991).

167. Peter Zablotsky, *Appropriate Role of Plaintiff Misuse in Products Liability Causes of Action*, 10 TOURO L. REV. 183, 191-92 (1993).

168. *See, e.g.*, Gangi v. Sears, Roebuck & Co., 360 A.2d 907 (Conn. Super. Ct. 1976); Calvert Fire Ins. Co. v. Fyr-Fyter Sales & Serv., 425 N.E.2d 910 (Ohio Ct. App. 1979).

169. Harville v. Anchor-Wate Co., 663 F.2d 598, 602 (5th Cir. 1981).

170. *See* Zablotsky, *supra* note 167, at 190-91; *see also* Simpson v. Standard Container Co., 527 A.2d 1337, 1340 (Md. Ct. Spec. App. 1987) (discussing multiple definitions of "misuse").

171. *See Simpson*, 527 A.2d at 1341 (quoting Ellsworth v. Sherne Lingerie, Inc., 495 A.2d 348, 354-55 (Md. 1985)).

172. *Ellsworth*, 495 A.2d at 355.

173. *Id.* at 354-55.

174. *Id.* at 355.

175. *Id.* at 354.

176. *Id.*

177. *Id.* at 353 (stating that "[m]ost jurisdictions have adopted the Restatement view that misuse is a factor in strict liability actions"). Comment h to section 402A of the Restatement states:

> A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable.

Misuse evolved within the doctrine of strict liability embodied in the Restatement (Second) of Torts section 402A.[178] Section 402A recognizes misuse as "a defense for the manufacturer where the user mishandles or misuses a product and thereby causes a dangerous condition."[179] Under this doctrine, the defendant must prove that the use occurred in an unintended manner or for an unintended purpose, that the use must not have been reasonably foreseeable by the manufacturer, and that the misuse caused the injury.[180]

This defense is similar to comparative fault or assumption of risk, which also involve an examination of the plaintiff's conduct.[181] Assumption of risk, a strict liability defense used when the plaintiff has "voluntarily and unreasonably proceed[ed] to encounter a known danger,"[182] focuses upon the plaintiff's culpability.[183] The plaintiff may not recover if he or she "voluntarily proceeds in the face of known danger."[184] Comparative fault is, essentially, the application of comparative negligence principles to other tort theories, such as strict liability.[185] Some courts have refused to apply this doctrine beyond negligence actions.[186]

Other courts, however, have used comparative fault principles to apportion the fault of each party, regardless of the theory of liability under which the plaintiff proceeds.[187] In other words, the manufacturer may

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RESTATEMENT (SECOND) OF TORTS § 402A cmt. h (1965).

178. Section 402A provides:

> Special Liability of Seller of Product for Physical Harm to User or Consumer
> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
> (a) the seller is engaged in the business of selling such a product, and
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
> (2) The rule stated in Subsection (1) applies although
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

179. *Id.*

180. *See* Zablotsky, *supra* note 167, at 191-93.

181. Toll, *supra* note 166, at 2307.

182. RESTATEMENT (SECOND) OF TORTS § 402A cmt. n.

183. Hughes v. Magic Chef, Inc., 288 N.W.2d 542, 545 (Iowa 1980).

184. *Id.*; *see also* Toll, *supra* note 166, at 2307 (defining assumption of the risk as "voluntarily and unreasonably proceeding to encounter a known danger").

185. *Id.*

186. *See, e.g.*, Melia v. Ford Motor Co., 534 F.2d 795, 802 (8th Cir. 1976) (observing that applying a comparative negligence statute in a strict liability case would be "extremely confusing and inappropriate"); Kinard v. Coats Co., 553 P.2d 835, 837 (Colo. Ct. App. 1976) (refusing to extend the application of comparative negligence principles to products liability actions under Restatement (Second) of Torts section 402A because such actions are not based upon negligence principles).

187. *See* Daly v. General Motors Corp., 575 P.2d 1162, 1172 (Cal. 1978) (extending comparative negligence principles to strict liability actions and recognizing the broad applicability of "fault" in both negligence and strict liability cases).

be relieved of liability in proportion to the user's misuse of the product.[188] Most jurisdictions, however, apply misuse as a complete bar to recovery.[189] The difficulty with applying comparative fault principles in strict liability arises because comparative fault neutralizes the impact and underlying purpose of a strict liability claim.[190] In some jurisdictions, comparative fault may allow some recovery in strict liability claims in cases where the plaintiff's misuse was either foreseeable or unforeseeable.[191]

Although most courts have adopted misuse in product liability actions in some form,[192] courts are split in determining whether the defendant must establish misuse as an affirmative defense, or if the plaintiffs must demonstrate an absence of misuse in cases of strict liability and negligence.[193] Courts which view misuse as a form of proximate cause place the burden on plaintiffs to show misuse did not occur,[194] and the plaintiffs must show that the misuse was unforeseeable to the defendant.[195]

The majority of jurisdictions, however, view misuse as a defendant's affirmative defense.[196] Generally, affirmative defenses require proof of all elements based upon the preponderance of the evidence, and the defendants are entitled to prevail even if the plaintiff proves all ele-

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188. The Model Uniform Products Liability Act, 44 Fed. Reg. 62,737 at § 112(c)(1); *see* 44 Fed. Reg. 62,737 (providing that when a manufacturer proves misuse as a cause of injury, damages are reduced or apportioned to the extent that the misuse caused the harm).

189. Note, however, that the highest courts in Kansas and Texas have completely rejected the misuse defense and supplanted it with comparative fault and contributory negligence. *See* Kennedy v. City of Sawyer, 618 P.2d 788, 798 (Kan. 1980) (holding that comparative liability statutes supplant the misuse defense); Duncan v. Cessna Aircraft Co., 665 S.W.2d 414, 427 (Tex. 1984) (holding that contributory negligence must be used to replace the misuse defense); *see also* Kavanaugh v. Southland Mower Co., 641 P.2d 258, 263 (Ariz. Ct. App. 1981) (noting that if proximate or legal cause of injury was misuse, and not product defect, there is no liability).

190. Zablotsky, *supra* note 167, at 199. "[S]trict liability focuses on the product rather than on the manufacturer's conduct. . . ." Toll, *supra* note 166, at 2307.

191. Toll, *supra* note 166, at 2308.

192. Ellsworth v. Sherne Lingerie, Inc., 495 A.2d 348, 353-54 (Md. 1985).

193. *Id.* at 354 (listing courts which have looked at causation and consequently categorized misuse as an affirmative defense).

194. Usually the plaintiff will allege that the product was defective or unreasonably dangerous. After this is established, the question becomes whether the harm "was within the risk created by the defective product." When the issue is stated as such, it becomes that of proximate cause, which is normally part of the plaintiff's burden of proof. James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1545-46 (1992).

195. *Id.* (stating that generally, in products liability cases, "the plaintiff is able to establish that the product was defective, and the question then becomes whether the harm was within the risk created by the defective product"); *see, e.g.*, *Ellsworth*, 495 A.2d at 356 (holding that misuse is not an affirmative defense because causation is an element of the plaintiff's case).

196. *See* Zablotsky, *supra* note 167, at 190. Of the 31 states that have addressed the issue of burden of proof with any degree of specificity or certainty, 20 view misuse as a defense and place the burden on the defendant. *Id.* at 201. The remaining 11 establish that disproving misuse is part of the plaintiff's prima facie case and place the burden on the defendant. *Id.* at 201-03.

ments of their case.[197] This concept becomes complicated, however, when applied to the misuse doctrine. For example, a plaintiff who proves that a defective product "caused" an injury is actually disproving that misuse caused the injury.[198] In this sense, misuse actually becomes "an inextricable part of the causation analysis in the plaintiff's case."[199]

B. *Tenth Circuit Cases*

1. *Allen v. Minnstar*[200]

a. *Facts*

In *Allen v. Minnstar*, the plaintiff fell overboard from a Wellcraft Marine boat manufactured by Outboard Marine Corporation (OMR), and the boat's unguarded propeller hit him.[201] He had been sitting in the bow of the boat and fell when the boat's driver accelerated and made a sharp turn in order to avoid an obstacle.[202] The plaintiff's left leg was so severely lacerated that amputation was required,[203] and he suffered abdominal injuries leading to a colostomy.[204] He then sued both Wellcraft and OMR for a variety of products liability claims.[205] The suit alleged that Wellcraft used a defective and unreasonably dangerous design,[206] and that the boat should have been equipped with a propeller guard and proper bow seating to prevent passenger ejection from the boat.[207] The court ruled in favor of OMR on summary judgment,[208] and the plaintiff's remaining claims against Wellcraft proceeded to a jury trial.[209]

Wellcraft raised the misuse defense,[210] asserting that the plaintiff was sitting on the gunwale of the boat rather than the bow seat.[211] The jury

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197. Toll, *supra* note 166, at 2308. For example, if the plaintiff in a contract case proves that a contract existed, it was breached, and damages occurred, the defendant will still win if he or she demonstrates that the statue of limitations expired three years before the suit was filed. *Id.*

198. *Id.* at 2309.

199. *Id.*

200. 97 F.3d 1365 (10th Cir. 1996).

201. *Minnstar*, 97 F.3d. at 1367.

202. *Id.*

203. *Id.*

204. *Id.*

205. *Id.*

206. *Id.*

207. *Id.*

208. *See* Allen v. Minnstar, Inc., 8 F.3d 1470, 1472-73 (10th Cir. 1993).

209. *Minnstar*, 97 F. 3d at 1367-68.

210. *Id.* at 1368. The trial transcript was not included in the record on appeal; therefore, the appeals court could not determine whether Allen objected to the introduction of the misuse defense during trial. The record did indicate that Allen filed written objections to the introduction of the defense. *Id.* at 1368 n.1.

211. *Id.* at 1368.

ruled in favor of Wellcraft, concluding that the boat was not unreasonably dangerous.[212]

b. *Decision*

On appeal, the Tenth Circuit upheld the jury verdict for Wellcraft and determined that foreseeability of product misuse was a jury question.[213] The court, applying Utah case law,[214] noted that state courts had yet to determine if foreseeability of misuse prevented the defense.[215] Noting that most states recognize the misuse defense and have generally established that foreseeability of misuse is a jury question, the Tenth Circuit upheld the decision.[216] The Tenth Circuit also noted that evidence of the plaintiff sitting on the gunwale rather than the seat of the boat was relevant as to whether the design of the boat's seating was the proximate cause of the injuries, regardless of the misuse defense.[217] Therefore, the court concluded, even had misuse not been used in the jury instructions, the issue was still highly relevant because it was necessary to establish the essential elements of the strict liability claim.[218]

2. *Staley v. Bridgestone/Firestone Inc.*[219]

a. *Facts*

In *Staley v. Bridgestone/Firestone Inc.*, an employee died after a multipiece tire and rim assembly explosively separated[220] while he was attempting to install a new tire on a road grader.[221] The decedent's estate brought suit against Firestone, claiming that it was foreseeable that such an explosion would occur,[222] and that the product was defective, unreasonably dangerous, and negligently designed.[223] Firestone's primary de-

212. *Id.* at 1367-68.

213. *Id.* at 1369.

214. *Id.* at 1368-69. The court acknowledged that the Utah Supreme Court recognized misuse as an affirmative defense in strict products liability. *Id.* at 1368 (citing Ernest W. Hahn v. Armco Steel Co., 601 P.2d 152, 158 (Utah 1979)). Utah also applies comparative fault principles to the misuse defense. *See* Mulherin v. Ingersoll-Rand Co., 628 P.2d 1301, 1303 (Utah 1981) (noting that the jury should be asked to consider "the relative burden each [party] should bear for the injury they have caused").

215. *Minnstar*, 97 F.3d at 1368.

216. *Id.* at 1368-69 (citing several cases holding that the determination of forseeability is a question for the jury).

217. *Id.* at 1369.

218. *Id.*

219. 106 F.3d 1504 (10th Cir. 1997).

220. *Staley*, 106 F.3d at 1507.

221. *Id.*

222. *Id.* at 1508.

223. *Id.* The plaintiff produced evidence showing that "if the components of the rim were assembled without being fully engaged, they might separate following the addition of inflation pressure." *Id.*

fense against Staley's estate was misuse,[224] alleging that the decedent failed to follow the suggested safety procedures.[225] Firestone also claimed that the decedent should have used the tire and rim restraint, not a hammer upon an inflated tire, and that the decedent mounted the tire contrary to his safety training.[226]

As support, Firestone introduced evidence showing that the decedent had signed a training record acknowledging his familiarity and prior training with such rims.[227] In addition, Firestone introduced significant evidence demonstrating the decedent's familiarity with proper safety procedures.[228] Finally, the defense brought forth statistics showing that the rim components in question had been involved in over ten million servicings with only eight recorded accidents.[229] The plaintiffs, however, argued that because Firestone could have reasonably foreseen the possibility of the decedent's conduct, Firestone could not assert the misuse defense.[230] The district court granted Firestone summary judgment on the failure-to-warn claim,[231] and the jury found for Firestone on the remaining claims.[232]

b. *Decision*

Upon reviewing the plaintiff's appeal, the Tenth Circuit recognized the three elements of misuse applicable under Colorado law:[233] (1) whether the use was for an unintended manner or for an unintended purpose; (2) whether the use was reasonably foreseeable to the manufacturer; and (3) whether the misuse caused the injury.[234] The plaintiffs asserted the misuse defense was inapplicable, because a similar accident had occurred in the past, making the possibility of the misuse foreseeable.[235] The court disagreed and held that misuse was not foreseeable to

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224. *Id.*
225. *Id.*
226. *Id.*
227. *Id.*
228. *Id.*
229. *Id.* at 1510.
230. *Id.*
231. *Id.* at 1508. Relying on *Cruz v. Texaco, Inc.*, 589 F. Supp. 777 (S.D. Ill. 1984), the district court held that the defendant was not strictly liable for failure to warn and had no duty to warn. *Cruz* held that a manufacturer of a winch truck would not be liable for the death of an employee because the decedent's employer was aware of the danger of the potential danger of driving at high speed with objects in tow and could have warned the employee. *Staley*, 106 F.3d at 1509.
232. *Id.* at 1508.
233. Colorado has adopted the Restatement's approach. *Id.* at 1510.
234. *Id.* (citing Uptain v. Huntington Lab, Inc., 723 P.2d 1322, 1325-26 (Colo. 1986)).
235. *Id.* The plaintiffs alleged that Firestone was aware of other injuries and deaths that resulted from conduct similar to Staley's conduct before his death. They cited a 1973 incident in which a lock ring was not properly seated, injured a manager who hit it with a hammer and relied upon Colorado Supreme Court decisions that found it was erroneous not to allow a misuse instruction after the plaintiffs produced evidence of prior reported incidents involving the same type of conduct. *Id.*

Firestone because of the low number of accidents occurring from the number of servicings.[236] Furthermore, the court relied upon the testimony of two defense experts that the decedent's actions were unforeseeable.[237]

Although the plaintiffs argued that one portion of the misuse jury instruction did not allow the jury to consider comparative fault and apportion the fault accordingly,[238] the court rejected this argument. The court determined that all elements of misuse were found, and comparative fault principles need only be applied if the jury determines one of the elements was not proven.[239]

3. *Daniel v. Ben E. Keith Co.*[240]

a. *Facts*

In *Daniel v. Ben E. Keith Company*, the Tenth Circuit addressed the principles of user foreseeability. The plaintiff alleged that she sustained injuries[241] while working in a restaurant preparing tortillas in a deep fat fryer.[242] After another employee accidentally poured bleach into the fryer,[243] the plaintiff suffered from exposure to the chlorine gas[244] and consequently was unable to work full time.[245] She filed a failure-to-warn claim against the manufacturer of the bleach, Ben E. Keith Company (Keith), alleging that the bleach was defective because its label did not adequately warn of such risks.[246] The defendant claimed that the other

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(citing Armentrout v. FMC Corp., 842 P.2d 175, 187-89 (Colo. 1992), and Schmutz v. Bolles, 800 P.2d 1307, 1316 (Colo. 1990)).

236. *Id.* In this case, the plaintiffs presented only one incident that involved hammering on this type of product. *Id.*

237. *Id.*

238. *Id.* The plaintiffs noted the Colorado pattern jury instruction which included the following:

> If you find that all of these three propositions have been proved, then your verdict must be for the manufacturer. (On the other hand, if you find that any of these three propostions has not been proved, you may still consider whether plaintiff's use of the product constitutes comparative fault, as that term is defined in these instructions).

Id. at 1510-11. The jury instruction submitted, however, included the following:

> A manufacturer of a product is not legally responsible for injuries or damages caused by a product if:
> The product was used in a manner other than that which was intended;
> That use could not reasonably have been expected by the manufacturer; and
> Such use rather than a defect, if any, in the product caused the plaintiff's claimed injuries or damages.

Id. at 1510.

239. *Id.*

240. 97 F.3d 1329 (10th Cir. 1996).

241. *Daniel*, 97 F.3d at 1331. The plaintiff claimed to suffer from Reactive Airway Dysfunction Syndrome (RADS). *Id.*

242. *Daniel*, 97 F.3d at 1331.

243. *Id.* at 1332.

244. *Id.*

245. *Id.*

246. *Id.* at 1331-32.

employee's negligent actions were the sole cause of the plaintiff's injuries.[247] The jury agreed and returned a verdict for the defendant.[248]

b. *Decision*

Upon review, the Tenth Circuit determined that the plaintiff must show that he would have read and heeded warnings on the label.[249] The court found that no such presumption existed in this case because the coworker testified that he was in a hurry at the time of the accident.[250] While acknowledging that manufacturers must anticipate all foreseeable uses of the product,[251] the court found this particular misuse to be unforeseeable, creating no duty to warn.[252]

C. *Other Circuits*

The Eighth Circuit also considered foreseeability as an element of misuse in *Chronister v. Bryco Arms*.[253] The plaintiff brought a products liability action subsequent to a gun accident, claiming that the gun was defectively designed.[254] In addition, the plaintiff argued that the manufacturer failed to warn of the possibility of the gun misfiring.[255] The manufacturer argued that, despite a recommendation on the packaging, the plaintiff misused the product by failing to wear ear protection.[256] After a trial, the jury found for the plaintiff on both strict liability and negligence claims.[257]

On appeal, the defendant argued that it was not reasonably foreseeable that a purchaser would use its handguns without wearing ear protection.[258] Additionally, the defendant asserted that use of a product that contradicted the product's warnings could not be considered a "reasonably anticipated" use.[259] The court disagreed, noting that basic products liability law dictated that a manufacturer cannot escape strict liability for

247. *Id.*
248. *Id.*
249. *Id.*
250. *Id.* at 1333.
251. *Id.* at 1334 (quoting Smith v. United States Gypsum Co., 612 P.2d 251, 254 (Okla. 1980)).
252. *Id.*
253. 125 F. 3d 624 (8th Cir. 1997).
254. *Chronister*, 125 F.3d at 625.
255. *Id.*
256. *Id.*
257. The jury apportioned five percent of the fault to Chronister on the strict liability claims and twenty-five percent on the negligence claim. *Id.*
258. *Id.* at 626-27.
259. *Id.* at 627.

a defective product that has foreseeably been misused,[260] and the judgment was affirmed.[261]

D. *Analysis*

The Tenth and Eighth Circuits agreed that the definition of misuse should involve some aspect of foreseeability.[262] The Tenth Circuit, however, did not clarify whether the misuse defense should be an affirmative defense, or part of the plaintiff's claim that must be disproved.[263]

The Tenth Circuit failed to clarify issues raised in *Allen v. Minnstar*. Initially, the court characterized misuse as if it were an affirmative defense and considered evidence introduced by the defendant to disprove liability.[264] Second, the court suggested that the defendant need not raise the defense at all because causation was "highly relevant" to establishing essential elements of the strict liability claim.[265] This analysis did not clarify the proper scope and application of the doctrine of misuse in products liability law.

CONCLUSION

The Tenth Circuit made significant contributions to products liability law during the survey period. A clear interpretation of *Medtronic* and the preemption doctrine will undoubtedly help consumers to assert state tort law claims against manufacturers of defective products. Similarly, *Yoder* provides courts and practitioners with guidance in applying the apparent manufacturer doctrine. The misuse defense, however, remains unclear in the wake of inconsistent interpretations, and courts will likely continue to struggle with this lack of clarity.

Lana Steven

260. *Id.*

261. *Id.* (finding that use of the gun without hearing protection was foreseeable, and thus the misuse defense could not be applied).

262. *See Chronister*, 125 F.3d at 627; Staley v. Bridgestone/Firestone, Inc., 106 F.3d 1504, 1510 (10th Cir. 1997); Allen v. Minnstar, Inc., 97 F.3d 1365, 1368 (10th Cir. 1996).

263. *See* Toll, *supra* note 166, at 2307 (1991).

264. *Minnstar*, 97 F.3d at 1368.

265. *Id.*